

REMARKS

Applicant notes with appreciation the withdrawal of the rejection under 35 U.S.C. 103(a) to claims 19-20 and 24 over Mantelle (US Patent No. 5,446,070) in view of Pomerantz (US Patent No. 5,081,157).

Claims 19-20 and 24-30 are the pending claims in the application.

Claims 19-20, 24, 26-27, and 30 are newly rejected under 35 U.S.C. 102(b) as being anticipated by Mantelle (US Patent No. 5,446,070). Additionally, claims 25 and 28-29 are newly rejected under 35 U.S.C. 103(a) as being un-patentable over Mantelle (US Patent No. 5,446,070) in view of Swinchart (US Patent No. 5,961,997).

**Remarks Directed to Rejection of Claims 19-20, 24, 26-27, and 30 under
35 U.S.C. §102(b) as Being Unpatentable over Mantelle**

The Office Action mailed on May 31, 2007 cites Mantelle for teaching a pharmaceutical formulation for topical administration of an anesthetic agent to ameliorate pain. Specifically, in Example 25 the ointment composition includes lecithin as emollient, propylene glycol as skin penetration enhancer, lidocaine base, tetracaine HCL as analgesic, and hydroxypropyl cellulose Klucel as gelling agent; in Example 16 the composition includes karaya gum as buffer, lecithin as emollient, propylene glycol as skin penetration enhancer, and lidocaine base; and in Example 28 the composition includes lecithin as emollient, propylene glycol as skin penetration enhancer, lidocaine base, and tetracaine HCL as analgesic.

Claims 19-20, 24, 26-27, and 30 in current form use the transitional phase "consisting of." The transitional phrase "consisting of" closes the claim to the inclusion of materials other than those recited in the claim. Stated differently, the transitional phrase "consisting of"

excludes any element, step, or ingredient not specified in the claim. (See MPEP 2111.03 in support of Applicant's position).

Turning to claims 19, 20, or 24, each of the claims excludes a salt of an anesthetic base, a binder, an anesthetic base in the form of prilocaine, a drug in the form of miconazole nitrate, a corticosteroid, an adrenocorticosteroid, or a keratolytic agent. In contrast, the teachings of the Mantelle patent provide examples wherein one or more of the above stated elements is included. For example, Example 25 of Mantelle includes an acid salt of tetracaine base; Example 16 of Mantelle includes a binder or bioadhesive in the form of lecithin and karaya gum; Example 28 of Mantelle includes an acid salt of tetracaine base.

Contrary to what is stated on page 3 of the Office Action that lecithin is an emollient and karaya gum is a buffer, lecithin is chemically a mixture of glycolipids, triglycerides, and phospholipids, and functionally used as surfactant, and is used as a binder in Mantelle (column 13 lines 54 -58). It should also be noted that karaya gum is taught and used as a bioadhesive but not as a buffer (column 15 lines 12-15); in fact, karaya gum hardly dissolves in water and therefore cannot possibly be a buffer.

As such, claims 19, 20 and 24 and any claims depending therefrom are not anticipated from Mantelle. Based on the above remarks, Applicant submits that all the pending claims are in allowable form. Reconsideration and withdrawal of the rejection of claims 19-20, 24, 26-27, and 30 under 35 U.S.C. §102(b) is solicited.

**Remarks Directed to Rejection of Claims 25 and 28-29 under
35 U.S.C. §103(a) as Being Unpatentable over Mantelle in view of Swinehart**

Applicant incorporates by reference the above remarks directed to Mantelle.

The Office Action cites that Mantelle teaches the anesthetic agents can comprise about 1 to about 50% by weight of the total composition, hence rendering obvious the claimed limitation of lidocaine being present from 0.5-6 total weight percent. Additionally, Swinehart is cited to bolster the limitation of Mantelle as to an anti-itching agent.

As discussed above, depending from claims 19 or 24 which uses the transitional phase “consisting of”, claims 25, 28, and 29 are deemed not obvious over Mantelle in view of Swinehart.

Additionally, Applicant submits that claims 25 and 29 are not obvious over Mantelle in view of Swinehart. The range of “about 1 to about 50% by weight” of the anesthetic agents in Mantelle, being a ranger broader than “0.5-6” of the claimed limitation, does not by itself render the narrower claimed limitation anticipated or obvious. *Atafina v. Great Lakes Chem. Corp.*, 441 F.3d 991, 999, 78 USPQ2d 1417, 1423 (Fed. Cir. 2006). In fact, “if the claims are directed to a narrow range, >and< the reference teaches a broad range ... it may be reasonable to conclude that the narrow range is not disclosed with ‘sufficient specificity’ to constitute an anticipation of the claims (MPEP 2131.03).

Furthermore, Applicant submits that claim 28 is not obvious over Mantelle in view of Swinehart the prior art reference combination of an anti-pruritic of Swinehart with an anesegic agent of Mantelle destroys the operation intended in Mantelle or Swinehart. See *In re Gordon*, 773 F.2d 900; 221 USPQ 1125 (Fed. Cir. 1984).

An antipruritic as evidenced in Mantelle (column 34 lines 10-15) is functionally operative only to substitute the anesthetic agent (column 23 lines 32-36). Stated differently, a functional

composition of Mantelle mandates the inclusion of an anesthetic agent such as a lidocaine, or a substituting drug such as an antipruritic, but not both. Conversely, combination of lidocaine and antipruritic in Swinehart mandates the composition be “oil-free” and “fragrance-free.” (column 2 lines 38-40 and 46-47) while fats and lipids such as lecithin are widely used in the compositions of Mantelle (Examples 26, 27, 28, 30, and 36).

As such, claims 25 and 28-29 are not obvious under 35 U.S.C. 103(a) over Mantelle in view of Swinehart. Reconsideration and withdrawal of the rejection of claims 25 and 28-29 under 35 U.S.C. §103(a) is solicited.

Summary

Claims 19, 20 and 24-30 are the claims pending in this application. The pending claims are believed to be in allowable form and directed to patentable subject matter. Reconsideration and allowance of the pending claims is solicited. Should the Examiner find to the contrary, she is respectfully requested to contact the undersigned attorney in charge of this application to resolve any remaining issues.

Dated: July 31, 2007

Respectfully submitted,

Electronic Signature: Avery N. Goldstein/
Avery N. Goldstein, Ph.D., Reg. No.: 39,204
GIFFORD, KRASS, SPRINKLE,
ANDERSON & CITKOWSKI, P.C.
2701 Troy Center Drive, Suite 330.
Post Office Box 7021
Troy, Michigan 48007-7021
(248) 647-6000

Attorney for Applicant